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Attorneys for Plaintiffs

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTELLAS PHARMA INC.; ASTELLAS US LLC; ASTELLAS PHARMA US, INC.; MEDIVATION LLC; MEDIVATION PROSTATE THERAPEUTICS LLC; THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, Plaintiffs, v. ZYDUS PHARMACEUTICALS (USA) INC.; ZYDUS LIFESCIENCES LTD., Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Astellas Pharma Inc., Astellas US LLC, and Astellas Pharma US, Inc. (collectively, "Astellas"), Medivation LLC and Medivation Prostate Therapeutics LLC (collectively, "Medivation"), and The Regents of the University of California ("The Regents") (all collectively, "Plaintiffs"), for their Complaint against Defendants Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Ltd. (collectively, "Zydus"), hereby allege as follows:

THE PARTIES

1. Plaintiff Astellas Pharma Inc. is a corporation organized and existing under the laws of Japan having its principal place of business at 2-5-1, Nihonbashi-Honcho, Chuo-Ku, Tokyo 103-8411, Japan.

2. Plaintiff Astellas US LLC is a limited liability company organized and existing under the laws of the State of Delaware having its principal place of business at 1 Astellas Way, Northbrook, Illinois 60062, United States.

3. Plaintiff Astellas Pharma US, Inc. is a corporation organized and existing under the laws of the State of Delaware having its principal place of business at 1 Astellas Way, Northbrook, Illinois 60062, United States.

4. Plaintiff Medivation LLC is a limited liability company organized and existing under the laws of the State of Delaware having its principal place of business at 235 East 42nd Street, New York, New York 10017, United States.

5. Plaintiff Medivation Prostate Therapeutics LLC is a limited liability company organized and existing under the laws of the State of Delaware having its principal place of business at 235 East 42nd Street, New York, New York 10017, United States.

6. Plaintiff The Regents of the University of California is a public corporation organized and existing under the laws of the State of California operating under Article 9, Section 9 of the California Constitution, having its corporate offices located at 1111 Franklin Street, Oakland, California 94607-5200, United States.

7. On information and belief, Defendant Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of the State of New Jersey having a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

8. On information and belief, Zydus Pharmaceuticals (USA) Inc., by itself and/or through its affiliates and agents, is in the business of among other things, manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

9. On information and belief, Defendant Zydus Lifesciences Ltd. is a corporation organized and existing under the laws of India having a principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar) Nr. Vaishnodevi Circle, Ahmedabad 382481, India.

10. On information and belief, Zydus Lifesciences Ltd., by itself and/or through its affiliates and agents, is in the business of among other things, manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

11. On information and belief, Zydus Pharmaceuticals (USA) Inc. is a wholly-owned subsidiary and the U.S. division of Zydus Lifesciences Ltd.

12. On information and belief, Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Ltd. are agents of each other with respect to the development, regulatory approval, marketing, sale, and/or distribution of generic products. On information and belief, the acts of Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Ltd. complained of herein were done with the cooperation, participation, and assistance of, and at least in part for the benefit of, each other.

13. On information and belief, Defendants Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Ltd. have cooperated and assisted in the preparation and filing of Zydus's Abbreviated New Drug Application ("ANDA") No. 217322 and will be involved in the

manufacture, importation, marketing, and sale of the drug that is the subject of ANDA No. 217322 if it is approved.

NATURE OF THE ACTION

14. This is a civil action for the infringement of United States Patent No. 7,709,517 ("the '517 patent") under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., arising from Zydus's filing of ANDA No. 217322 with the United States Food and Drug Administration ("FDA") seeking approval to market generic versions of the pharmaceutical products Xtandi® tablets, 40 and 80 mg, before the expiration of the '517 patent covering Xtandi®.

JURISDICTION AND VENUE

15. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

16. This Court has personal jurisdiction over Zydus by virtue of the fact that, *inter alia*, Zydus has committed the tortious act of patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) that has led to foreseeable harm and injury to Plaintiffs in the State of New Jersey and throughout the United States.

17. This Court has personal jurisdiction over Zydus Pharmaceuticals (USA) Inc. On information and belief, Zydus Pharmaceuticals (USA) Inc. is a New Jersey corporation having a principal place of business in New Jersey.

18. This Court has personal jurisdiction over Zydus by virtue of the fact that Zydus is at home in New Jersey as reflected by the fact that, on information and belief, it regularly does or solicits business in New Jersey, engages in other persistent courses of conduct in New Jersey, and/or derives substantial revenue from services or things used or consumed in New Jersey, including by selling its pharmaceutical products in New Jersey and, therefore, can reasonably

expect to be subject to jurisdiction in the New Jersey courts. Among other things, on information and belief, Zydus conducts marketing and sales activities in the State of New Jersey, including but not limited to, distribution, marketing, and sales of pharmaceutical products to New Jersey residents that are continuous and systematic. On information and belief, if Zydus's ANDA No. 217322 is approved, it will market and sell its generic versions of Xtandi® tablets in New Jersey.

19. This Court also has personal jurisdiction over Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Ltd. (formerly known as Cadila Healthcare Ltd.) by virtue of the fact that each previously submitted to the jurisdiction of this Court and availed itself of this Court by consenting to this Court's jurisdiction and asserting counterclaims in civil actions initiated in this jurisdiction including, but not limited to, *e.g.*, *Supernus Pharm., Inc., v. Zydus Pharm. (USA) Inc.*, No. 3:21-cv-17104 (D.N.J.); *Almirall, LLC v. Zydus Pharm. (USA) Inc.*, No. 3:20-cv-00343 (D.N.J.); *Takeda Pharm. Co. v. Zydus Pharm. (USA) Inc.*, No. 3:18-cv-11792 (D.N.J.); *Shionogi Inc. v. Zydus Pharm. (USA) Inc.*, No. 3:18-cv-12898 (D.N.J.); *Valeant Pharm. North America LLC v. Zydus Pharm. (USA) Inc.*, No. 2:18-cv-13635 (D.N.J.); and *Takeda Pharm. Co. v. Zydus Pharm. (USA) Inc*., No. 3:18-cv-01994 (D.N.J.). On information and belief, Zydus Pharmaceuticals (USA) Inc. has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of New Jersey by having filed suit in this jurisdiction. *See, e.g.*, *Zydus Pharm. USA, Inc. v. Eli Lilly & Co.*, 2:10-cv-05584 (D.N.J.).

20. Alternatively, assuming that the above facts do not establish personal jurisdiction over Zydus Lifesciences Ltd., this Court may exercise jurisdiction over Zydus Lifesciences Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Zydus Lifesciences Ltd. is a foreign defendant not subject to general personal

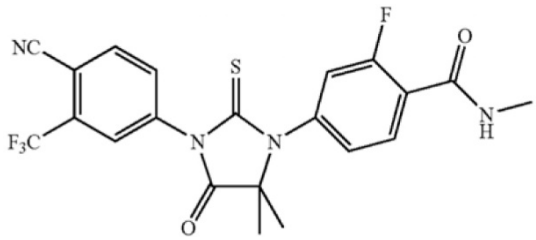
jurisdiction in the courts of any state; and (c) Zydus Lifesciences Ltd. has sufficient contacts with the United States as a whole, including but not limited to manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Zydus Lifesciences Ltd. satisfies due process.

21. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE XTANDI® TABLET NDA

22. Astellas Pharma US, Inc. filed New Drug Application ("NDA") No. 213674 for Xtandi® (enzalutamide) tablets, 40 mg and 80 mg. The FDA approved NDA No. 213674 for Xtandi® 40 mg and 80 mg tablets on August 4, 2020 for the treatment of patients with castration-resistant prostate cancer and metastatic castration-sensitive prostate cancer. Xtandi® tablets are sold and co-promoted by Astellas Pharma US, Inc. and Pfizer Inc. in the United States.

23. Enzalutamide is a compound that can be referred to by any of several chemical names, including 4-{3-[4-cyano-3-(trifluoromethyl)phenyl]-5,5-dimethyl-4-oxo-2-sulfanylideneimidazolidin-1-yl}-2-fluoro-N-methylbenzamide, 4-{3-(4-cyano-3-(trifluoromethyl)phenyl)-5,5-dimethyl-4-oxo-2-thioxoimidazolidin-1-yl}-2-fluoro-N-methylbenzamide, 4-[3-[4-cyano-3-(trifluoromethyl)phenyl]-4-keto-5,5-dimethyl-2-thioxo-imidazolidin-1-yl]-2-fluoro-N-methyl-benzamide, and 4-[3-[4-cyano-3-(trifluoromethyl)phenyl]-5,5-dimethyl-4-oxo-2-sulfanylidene-1-imidazolidinyl]-2-fluoro-N-methylbenzamide, and which has the following chemical structure:



THE PATENT-IN-SUIT

24. On May 4, 2010, the '517 patent, entitled "Diarylhydantoin Compounds," was duly and legally issued to The Regents. A true and correct copy of the '517 patent is attached hereto as Exhibit A.

25. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the '517 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book") for Xtandi® 40 mg and 80 mg tablets.

26. Pursuant to an agreement, as amended, entered into between Medivation, Inc., Medivation Prostate Therapeutics, Inc., and The Regents, Medivation, Inc. and Medivation Prostate Therapeutics, Inc. were granted an exclusive license to the '517 patent, with the right to sue for infringement of the '517 patent in the United States.

27. Pursuant to an agreement entered into between Astellas Pharma Inc., Medivation, Inc., and Medivation Prostate Therapeutics, Inc., Astellas Pharma Inc. was granted an exclusive sublicense to the '517 patent, with the right to sue for infringement of the '517 patent in the United States.

28. Pursuant to an agreement entered into between Astellas Pharma Inc. and Astellas US LLC, Astellas US LLC was granted a sublicense to the '517 patent, with the right to sue for infringement of the '517 patent in the United States.

29. On September 28, 2016, Pfizer Inc. acquired Medivation, Inc. and its wholly owned subsidiary Medivation Prostate Therapeutics, Inc.

30. On August 28, 2017, Medivation, Inc. filed a Certificate of Conversion with the Delaware Secretary of State, in which Medivation, Inc. converted from a corporation to a limited liability company and changed its name to Medivation LLC.

31. On August 28, 2017, Medivation Prostate Therapeutics, Inc. filed a Certificate of Conversion with the Delaware Secretary of State, in which Medivation Prostate Therapeutics, Inc. converted from a corporation to a limited liability company and changed its name to Medivation Prostate Therapeutics LLC.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

32. By a letter dated May 26, 2022 (the "Zydus Notice Letter"), Zydus advised Astellas and The Regents that it had submitted ANDA No. 217322 to the FDA seeking approval to manufacture, use, or sell enzalutamide 40 mg and 80 mg tablets ("Zydus's Generic Products") prior to the expiration of the '517 patent.

33. On information and belief, Zydus submitted ANDA No. 217322 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act, seeking approval to engage in the commercial manufacture, use, and sale of Zydus's Generic Products as generic versions of Xtandi® 40 mg and 80 mg tablets.

34. On information and belief, ANDA No. 217322 seeks FDA approval of Zydus's Generic Products for the indications of treatment of castration-resistant prostate cancer and metastatic castration-sensitive prostate cancer.

35. The Zydus Notice Letter also advised Astellas and The Regents that Zydus's ANDA submission included certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in Zydus's opinion, certain claims of the '517 patent are invalid, unenforceable, and/or not infringed.

36. The Zydus Notice Letter does not allege non-infringement of certain claims of the '517 patent.

37. By not identifying non-infringement defenses for certain claims of the '517 patent in the Zydus Notice Letter, Zydus admits Zydus's Generic Products meet all limitations of those claims.

38. The Zydus Notice Letter does not allege invalidity of certain claims of the '517 patent.

39. By not identifying invalidity defenses for certain claims of the '517 patent in the Zydus Notice Letter, Zydus admits the claims of the '517 patent for which invalidity defenses have not been raised are valid.

40. The Zydus Notice Letter does not allege invalidity under 35 U.S.C. §§ 101, 102, or 112, or unenforceability of any claim of the '517 patent.

41. By not identifying invalidity defenses under 35 U.S.C. §§ 101, 102, or 112, or unenforceability defenses for the '517 patent in the Zydus Notice Letter, Zydus admits the claims of the '517 patent are valid under 35 U.S.C. §§ 101, 102, and 112, and are enforceable.

42. There is an actual, real, immediate, and justiciable controversy between Plaintiffs and Zydus regarding the infringement, validity, and enforceability of the '517 patent.

43. Plaintiffs are commencing this action within 45 days of receiving the Zydus Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I
(Infringement of the '517 Patent)

44. Plaintiffs incorporate each of the preceding paragraphs 1 to 43 as if fully set forth herein.

45. By submitting ANDA No. 217322 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's Generic Products throughout the United States, including New Jersey, prior

to expiration of the '517 patent, Zydus committed an act of infringement of the '517 patent under 35 U.S.C. § 271(e)(2)(A).

46. The '517 patent claims, *inter alia*, the compound, and pharmaceutical compositions of, enzalutamide.

47. On information and belief, Zydus's Generic Products, if approved by the FDA, will contain the compound enzalutamide and/or pharmaceutical compositions thereof, which will constitute infringement of claims of the '517 patent.

48. On information and belief, Zydus's manufacture, use, sale, offer for sale, and/or importation into the United States of Zydus's Generic Products prior to the expiration of the '517 patent, including any applicable exclusivities or extensions, will directly infringe the '517 patent under 35 U.S.C. § 271(a). Zydus will infringe one or more of the claims of the '517 patent.

49. On information and belief, Zydus's Generic Products will infringe at least Claim 1 of the '517 patent which recites "[a] compound selected from the group consisting of" a group of compounds including enzalutamide. On information and belief, Zydus's Generic Products will infringe Claim 1 of the '517 patent because Zydus's Generic Products will contain enzalutamide.

50. On information and belief, Zydus was aware of the existence of the '517 patent and its listing in the Orange Book as demonstrated by Zydus's reference to the '517 patent in the Zydus Notice Letter.

51. On information and belief, Zydus knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's Generic Products prior to patent expiry will infringe one or more claims of the '517 patent.

52. On information and belief, Zydus's statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the '517 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

53. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Zydus has infringed one or more claims of United States Patent No. 7,709,517 by submitting ANDA No. 217322 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's Generic Products before the expiration of that patent under 35 U.S.C. § 271(e)(2)(A);

B. A judgment that Zydus's commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of Zydus's Generic Products will infringe one or more claims of United States Patent No. 7,709,517 under 35 U.S.C. §§ 271(a);

C. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283 restraining and enjoining Zydus, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from engaging in the commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of Zydus's Generic Products prior to the expiration date of United States Patent No. 7,709,517, inclusive of any extensions;

D. An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 217322 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of United States

Patent No. 7,709,517, inclusive of any extensions;

E. A declaration that this case is "exceptional" under 35 U.S.C. § 285 and an award of attorney fees;

F. An award of costs and expenses in this action; and

G. Such other and further relief as the Court may deem just and proper.

Dated: July 8, 2022

/s/ Liza M. Walsh
Liza M. Walsh
Katelyn O'Reilly
Jessica K. Formichella
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LOCAL RULE 11.2 CERTIFICATION

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending litigation in any court, administrative proceeding, or arbitration proceeding, nor are there any non-parties known to Plaintiffs that should be joined to this action, but this action is related to the following action:

- *Astellas Pharma Inc., et al. v. Sandoz Inc.*, Case No. 2:21-cv-13177 (JMV-JSA), pending in the United States District Court for the District of New Jersey.

Dated: July 8, 2022

/s/ Liza M. Walsh
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LOCAL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seek, *inter alia*, injunctive relief.

Dated: July 8, 2022

/s/ Liza M. Walsh
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